Patent Claims

We Claim:

1) A pharmaceutical composition comprising one or more anticholinergics (1) combined with one or more dopamine agonists (2), each optionally in the form of the enantiomers, mixtures of the enantiomers or in the form of the racemates thereof, and each optionally in the form of the solvates or hydrates thereof, and each optionally together with one or more pharmaceutically acceptable excipients, and wherein substances (1) and (2) are present either together in a single formulation or separately in two separate formulations.

2) A pharmaceutical composition according to claim 1, characterised in that the substances 1 and 2 are present together in a single formulation.

3) A pharmaceutical composition according to claim 1, characterised in that the substances 1 and 2 are present separately in two separate formulations.

4) A pharmaceutical composition according to claim 1, characterised in that 1 is selected from tiotropium salts, oxitropium salts and ipratropium salts.

5) A pharmaceutical composition according to claim 1, characterised in that 1 is present in the form of a chloride, bromide, iodide, methanesulphonate or paratoluene sulphonate salt.

6) A pharmaceutical composition according to claim 5, characterised in that 1 is present in the form of a bromide salt.

7) A pharmaceutical composition according to claim 1, characterised in that 1 is selected from tiotropium bromide, oxitropium bromide and ipratropium bromide.

8) A pharmaceutical composition according to claim 1, characterised in that 2 is selected from among bromocriptin, cabergolin, alpha-dihydroergocryptin, lisuride, pergolide, pramipexol, roxindol, ropinirol, terguride, talipexol and viozan.

9) A pharmaceutical composition according to claim 1, characterised in that 2 is selected from pramipexol, talipexol and viozan.

10) A pharmaceutical composition according to claim 1, characterised in that 2 is selected from dopamine agonists which do not overcome the blood-brain barrier and are primarily characterised by a peripheral activity.

11) A pharmaceutical composition according to claim 10, characterised in that 2 is selected from among dopamine, fenoldopam, dopexamine, CHF 1035, tolnaperisine and RU-40021.

12) A pharmaceutical composition according to claim 1, characterised in that the weight ratios of 1 to 2 are in the range from 1:300 to 50:1.

13) A pharmaceutical composition according to claim 1, characterised in that the weight ratios of 1 to 2 are in the range from 1:250 to 40:1.

14) A pharmaceutical composition according to claim 1, characterised in that a single administrative form of the

composition contains a dose of the active substance combination of 1 and 2 of 0.01 to 10000μg.

15) A pharmaceutical composition according to claim 1, characterised in that a single administrative form of the composition contains a dose of the active substance combination of 1 and 2 of 0.1 to 2000μg.

16) A pharmaceutical composition according to claim 1, characterised in that it is in the form of a formulation suitable for inhalation.

17) A pharmaceutical composition according to claim 16, characterised in that it is a formulation selected from among inhalable powders, propellant-containing inhalable aerosols and propellant-free inhalable solutions or suspensions.

18) A pharmaceutical composition according to claim 17, characterised in that it is an inhalable powder which comprises 1 and 2 in admixture with suitable physiologically acceptable excipients selected from among monosaccharides, disaccharides, oligo- and polysaccharides, polyalcohols, salts, or mixtures of these excipients with one another.

19) An inhalable powder according to claim 18, characterised in that the excipients have a maximum average particle size of up to 250μm.

20) An inhalable powder according to claim 18, characterised in that the excipients have a maximum average particle size of between 10 and 150μm.

21) A capsule containing an inhalable powder according to claim 18.

22) A pharmaceutical composition according to claim 17, characterised in that it is an inhalable powder which contains only the active substances 1 and 2 as its ingredients.

23) A pharmaceutical composition according to claim 17, characterised in that it is a propellant-containing inhalable aerosol which contains 1 and 2 in dissolved or dispersed form.

24) A propellant-containing inhalable aerosol according to claim 23, characterised in that it contains a propellant gas selected from hydrocarbons and halohydrocarbons.

25) A propellant-containing inhalable aerosol according to claim 24, wherein the propellant gas is selected from n-propane, n-butane, isobutane, or fluorinated derivatives of methane, ethane, propane, butane, cyclopropane or cyclobutane.

26) A propellant-containing inhalable aerosol according to claim 24, characterised in that the propellant gas is TG134a, TG227 or a mixture thereof.

27) A propellant-containing inhalable aerosol according to claim 23, characterised in that it optionally contains one or more other ingredients selected from among cosolvents, stabilisers, surfactants, antioxidants, lubricants and pH adjusters.

28) A propellant-containing inhalable aerosol according to claim 23, characterised in that it contains up to 5 wt.% of 1 and/or 2.

29) A pharmaceutical composition according to claim 17, characterised in that it is a propellant-free inhalable solution or suspension which further comprises a solvent selected from water, ethanol or a mixture of water and ethanol.

30) An inhalable solution or suspension according to claim 29, characterised in that the pH is 2 - 7.

31) An inhalable solution or suspension according to claim 29, characterised in that the pH is 2 -5.

32) An inhalable solution or suspension according to claim 30, characterised in that the pH is adjusted by means of an acid selected from among hydrochloric acid, hydrobromic acid, nitric acid, sulphuric acid, ascorbic acid, citric acid, malic acid, tartaric acid, maleic acid, succinic acid, fumaric acid, acetic acid, formic acid and propionic acid or mixtures thereof.

33) An inhalable solution or suspension according to claim 29, characterised in that it optionally contains other co-solvents and/or excipients.

34) An inhalable solution or suspension according to claim 33, characterised in that it contains as co-solvents ingredients which contain hydroxyl groups or other polar groups.

35) An inhalable solution or suspension according to claim 33, wherein the co-solvents are selected from alcohols and glycols.

36) An inhalable solution or suspension according to claim 33, wherein the co-solvents are selected from isopropyl alcohol, propyleneglycol, polyethyleneglycol, polypropyleneglycol, glycolether, glycerol, polyoxyethylene alcohols and polyoxyethylene fatty acid esters.

37) An inhalable solution or suspension according to claim 33, characterised in that it contains as excipients surfactants, stabilisers, complexing agents, antioxidants, preservatives, flavorings, pharmacologically acceptable salts and/or vitamins.

38) An inhalable solution or suspension according to claim 37, characterised in that it contains a complexing agent selected from editic acid or a salt of editic acid.

39) An inhalable solution or suspension according to claim 38, characterised in that the complexing agent is sodium edetate.

40) An inhalable solution or suspension according to claim 37, characterised in that it contains an antioxidant selected from among ascorbic acid, vitamin A, vitamin E and tocopherols.

41) An inhalable solution or suspension according to claim 37, characterised in that it contains a preservative selected from cetyl pyridinium chloride, benzalkonium chloride, benzoic acid and benzoates.

42) An inhalable solution or suspension according to claim 33, characterised in that it contains, in addition

to the active substances 1 and 2 and the solvent, only benzalkonium chloride and sodium edetate.

43) An inhalable solution or suspension according to claim 33, characterised in that it contains, in addition to the active substances 1 and 2 and the solvent, only benzalkonium chloride.

44) An inhalable solution or suspension according to claim 29, characterised in that it is a concentrate or a sterile ready-to-use inhalable solution or suspension.

45) An inhaler comprising a capsule according to claim 21.

46) An inhaler comprising an inhalable solution according to claim 29.

47) An energy-operated free-standing or portable nebulizer which produces inhalable aerosols by means of ultrasound or compressed air, comprising an inhalable solution according to claim 44.

48) A method of treating inflammatory or obstructive diseases of the respiratory tract, or cystic fibrosis, in a patient in need thereof, comprising administering to said patient a therapeutically effective amount of a pharmaceutical composition according to claim 1.